

line 23: replace "norgestril" with --norgestrel--;  
 line 31: replace "gestogens" with --gestagens--; and  
 line 33: replace "progestogens" with --progestagens--.  
 Page 10, line 1: replace "enzyl" with --enyl--; and  
 line 8: replace "antigestations" with --antigestagens--.  
 Page 13, line 1: replace "antiprogesting" with --antiprogestin--.  
 Page 15, line 24: replace "continuous the" with --the continuous--.  
 Page 16, line 11: delete "that".  
 Page 17, line 4: replace "de-tection" with --detection--.  
 Page 18, line 30: replace "were" with --was--.  
 Page 20, line 36: replace "bleed" with --bleeding--.  
 Page 21, line 13: replace "accu-mulation" with --accumulation--.  
 Page 23, line 9: replace "single-estradiol containing" with --single  
 estradiol-containing--;  
 line 12: replace "remain" with --remains--;  
 line 20: replace "onpristone" with --onapristone--.  
 Page 25, line 11: after "im" insert --,--; and  
 line 29: replace "progesting" with --progestin--.  
 Page 26, line 13: replace "vention" with --ventional--.

### IN THE CLAIMS:

Claims 1-27: Cancel the claims and replace them with the following

claims:

82. A method of avoiding the bleeding problems associated with administering to a female mammal dosage amounts of an estrogen low enough to create incidents of breakthrough bleeding and withdrawal amenorrhea, which comprises (a) administering the estrogen daily without interruption and (b) periodically, at intervals of at least about a month, administering to the female an amount of an antiprogestin effective to reduce or eliminate breakthrough bleeding and, optionally, to induce sloughing of accumulated endometrial tissue and thereby induce menses.

83. The method of claim 82, wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

84. The method of claim 82, wherein the female mammal is a gonadal woman desiring contraception.

85. The method of claim 84, wherein the estrogen is administered in combination with a progestin.

86. The method of claim 85, wherein the amounts of the estrogen and the progestin which are administered are effective to suppress endometrial proliferation.

87. The method of claim 85, wherein the administration of the progestin is continued uninterrupted throughout the cycle. 112 No Antbl

88. The method of claim 85, wherein the administration of the progestin is interrupted proximate the day of antiprogestin administration. 112?

89. The method of claim 84, wherein the antiprogestin is administered about monthly.

90. The method of claim 84, wherein the antiprogestin is administered orally.

91. The method of claim 84, wherein the antiprogestin is onapristone or mifepristone.

92. The method of claim 85, wherein the progestin is gestodene or norethindrone acetate.

93. The method of claim 85, wherein the estrogen, the progestin and the antiprogestin are administered orally; wherein the administration of the progestin and the estrogen is continued uninterrupted throughout the cycle and wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

112  
no issue

94. The method of claim 82, wherein the female is a para- or postmenopausal woman on hormone replacement therapy.

95. The method of claim 94, wherein the estrogen is administered in combination with a progestin.

96. The method of claim 95, wherein the administration of the progestin is continued uninterrupted during the period of antiprogestin administration.

97. The method of claim 95, wherein the administration of the progestin is interrupted proximate the period of antiprogestin administration.

112

98. The method of claim 94, wherein the antiprogestin is onapristone or mifepristone.

99. The method of claim 94, wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

01/18/88 FAX 14:58 FAX 100 240 0410 MILLER, WHITE et al 007

100. The method of claim 95, wherein the antiprogesterin is onapristone or mifepristone; and wherein the progestin is gestodene or norethindrone acetate.

101. The method of claim 95, wherein the estrogen, progestin and antiprogesterin are administered orally; wherein the antiprogesterin is administered at longer than one month intervals; wherein the administration of the progestin is continued uninterrupted during the period of antiprogesterin administration; and wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

102. A kit containing at least about 20 estrogen and progestin-containing tablets, which collectively are effective when taken on successive days to achieve continuous oral contraception in a gonadal female human being but which contain amounts thereof which are too low to avoid breakthrough bleeding incidents where administration of the tablets is interrupted for a week during each monthly cycle to induce menses; and containing a tablet, arranged in the kit so as to be taken after at least 20 of the estrogen and progestin-containing tablets have been taken, which contains an amount of an antiprogesterin effective to induce menses.

NO  
ANTI PROG  
E1 cont

103. A kit according to claim 102, containing 28 of the estrogen and progestin-containing tablets, arranged to be taken sequentially with the antiprogesterin-containing tablet positioned as the 20th or later tablet in the sequence.

104. A kit according to claim 102, wherein the antiprogesterin is onapristone or mifepristone; and wherein the progestin is gestodene or norethindrone acetate.

112 NO  
ANTI PROG

105. A kit according to claim 102, wherein the estrogen and the daily dose thereof is ethinyl estradiol or estradiol or an ester thereof in the amount of 5-15 mcg/day, mestranol in the amount of 20-25 mcg/day or conjugated estrogens in the amount of 5-15 mcg/day.

106. A pharmaceutical composition in solid oral unit dosage form comprising amounts of an estrogen and of a progestin contraceptively equivalent to 5 mcg to 35 mcg of ethinyl estradiol and 0.5 mg to 1.5 mg of norethindrone acetate, respectively and an amount of an antiprogesterin effective to induce menses in a female human being who has ingested daily, for at least 20 days, corresponding amounts of the estrogen and the progestin.

107. A pharmaceutical composition according to claim 106, containing (a) 5-15 mcg of estradiol or ethinyl estradiol or an ester thereof; (b) 0.5 to 0.75 mg norethindrone acetate or 10 to 15 mcg of gestodene; and (c) 50 to 500 mg of onapristone or mifepristone.

Amend claims 42, 48 and 49 as follows:

42. A method of hormone replacement therapy or contraception [fertility control], comprising administering to a woman in need thereof an effective amount of estrogen, alone or in combination with an effective amount of a progestin, and an amount of antiprogesterin effective to ameliorate uterine bleeding [control] problems associated with hormone replacement therapy or contraception.

Claim 48, line 2: replace "fertility control" with --contraception--.

49. A method of achieving contraception [fertility control] in a woman comprising administering to a woman in need thereof an effective amount of progestin and an amount of antiprogesterin effective to ameliorate uterine bleeding [control] problems associated with contraception.